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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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GALITSKY, NIKOLAI M

[REDACTED] ART UNIT

[REDACTED] PAPER NUMBER

1631

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9

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/580,491 Examiner Nikolai M Galitsky	HERTOGS ET AL. Art Unit 1631
-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --		
<b>Period for Reply</b>		
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.		
<ul style="list-style-type: none"> <li>- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.</li> <li>- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.</li> <li>- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.</li> <li>- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).</li> <li>- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).</li> </ul>		
<b>Status</b>		
<p>1)<input checked="" type="checkbox"/> Responsive to communication(s) filed on <u>17 September 2001</u>.</p> <p>2a)<input type="checkbox"/> This action is FINAL.                            2b)<input checked="" type="checkbox"/> This action is non-final.</p> <p>3)<input type="checkbox"/> Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i>, 1935 C.D. 11, 453 O.G. 213.</p>		
<b>Disposition of Claims</b>		
<p>4)<input checked="" type="checkbox"/> Claim(s) <u>1-30</u> is/are pending in the application.</p> <p>4a) Of the above claim(s) <u>1-6 and 8-30</u> is/are withdrawn from consideration.</p> <p>5)<input type="checkbox"/> Claim(s) _____ is/are allowed.</p> <p>6)<input checked="" type="checkbox"/> Claim(s) <u>7</u> is/are rejected.</p> <p>7)<input type="checkbox"/> Claim(s) _____ is/are objected to.</p> <p>8)<input type="checkbox"/> Claim(s) _____ are subject to restriction and/or election requirement.</p>		
<b>Application Papers</b>		
<p>9)<input type="checkbox"/> The specification is objected to by the Examiner.</p> <p>10)<input type="checkbox"/> The drawing(s) filed on _____ is/are: a)<input type="checkbox"/> accepted or b)<input type="checkbox"/> objected to by the Examiner.</p> <p style="margin-left: 20px;">Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).</p> <p>11)<input type="checkbox"/> The proposed drawing correction filed on _____ is: a)<input type="checkbox"/> approved b)<input type="checkbox"/> disapproved by the Examiner.</p> <p style="margin-left: 20px;">If approved, corrected drawings are required in reply to this Office action.</p> <p>12)<input type="checkbox"/> The oath or declaration is objected to by the Examiner.</p>		
<b>Priority under 35 U.S.C. §§ 119 and 120</b>		
<p>13)<input type="checkbox"/> Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</p> <p>a)<input type="checkbox"/> All    b)<input type="checkbox"/> Some *    c)<input type="checkbox"/> None of:</p> <p style="margin-left: 20px;">1.<input type="checkbox"/> Certified copies of the priority documents have been received.</p> <p style="margin-left: 20px;">2.<input type="checkbox"/> Certified copies of the priority documents have been received in Application No. _____.</p> <p style="margin-left: 20px;">3.<input type="checkbox"/> Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</p> <p>* See the attached detailed Office action for a list of the certified copies not received.</p> <p>14)<input type="checkbox"/> Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).</p> <p>a)<input type="checkbox"/> The translation of the foreign language provisional application has been received.</p> <p>15)<input type="checkbox"/> Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.</p>		
<b>Attachment(s)</b>		
<p>1)<input checked="" type="checkbox"/> Notice of References Cited (PTO-892)</p> <p>2)<input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</p> <p>3)<input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) <i>Replies to 3 sheets</i></p> <p>4)<input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____</p> <p>5)<input type="checkbox"/> Notice of Informal Patent Application (PTO-152)</p> <p>6)<input type="checkbox"/> Other: _____</p>		

Serial Number: 09/580,491

Art Unit: 1631

### **DETAILED ACTION**

The art unit designated for this application has changed. Applicant(s) are hereby informed that future correspondence should be directed to Art Unit 1631.

### **RESPONSE TO RESTRICTION REQUIREMENT**

Applicants elections with traverse of Group II, (Mutations 103S, 118I, 88T) in Paper Nos. 5 and 8, filed April 27, 2001; and Sep 17, 2001; respectfully; are acknowledged. The traversal is on the ground(s) that Groups II, III, IV, and V are classified as part of the same class, i.e., 435 and Groups III, IV, and V are as part of the same class and the same subclass, i.e., class 435, subclass 5. This is not found persuasive because the restriction Groups are patentably distinct over each other due to the different subject matter from Group to Group. For instance, Group II is drawn to a method of evaluating the effectiveness of anti-HIV therapy, Group III is drawn to a method of screening for the drug against NNRTI resistant strains of HIV, Group IV is drawn to a method of screening for the drug against NRTI resistant strains of HIV, and Group V is drawn to a method of screening for the drug against PI resistant strains of HIV. The basis for separate restriction grouping clearly was

previously set forth as differences in the methods as summarized above. Applicants' traversal argument is not directed to this basis for restriction and therefore moot.

Also, each class/subclass such as 435/5 encompasses a multitude of inventions.

It is noted that mutations, as elected, of 103S, 118I, and 88T are separate selections in claim 7. However, claims 8-11 all require the evaluation of non-elected mutations, such as 101P etc. and are therefore withdrawn from examination at this time as being directed to non-elected mutations subject matter. Applicants' are, however, reminded that the mutation election is a species election and future examination of the other mutation species in the claims will occur if the elected species correspond to allowable subject matter. Claims 1-6 and 12-30 are also withdrawn from examination as being directed to non-elected subject matter. They cannot be searched together without serious and undue burden.

The requirement is still deemed proper and is therefore made FINAL.

### **Priority**

Acknowledgment is made of applicants claim the right to priority under 35 U.S.C 119(e) based on Provisional Patent Application No. 60.136,743, filed on May 28, 1999.

### ***Claim Rejections - 35 USC§ 112, first paragraph.***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 7 is rejected under 35 U.S.C. 112, first paragraph, because the

specification, while being enabling for a method of evaluating the effectiveness of antiretroviral therapy of an HIV-infected patient with the 118I mutation, does not reasonably provide enablement for the correlation of resistance regarding mutation 103S and 88T. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below. The claimed invention is drawn to a method of evaluating the effectiveness of an antiviral therapy of an HIV-infected patient comprising of three steps. The evaluation would necessitate a guidance to formulate result(s). For instance, the step

(ii) of claim 7 include mutations (a) 103S, (b) 118I, and © 88T and table 5, page 35 reports the frequency of ZDV and 3TC resistance-correlated mutations 118I, and etc., but only allegation of reporting resistance correlations for mutations 103S and 88T without supporting evidence. Therefore, performing the method of evaluating of effectiveness lacks enablement and thus is undue experimentation that would require patient evaluation, which is undue experimentation for determining resistance correlation to mutation presence.

Claim 7 is rejected, as discussed below, under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 (lines 14 & 15) "... mutation chosen from 88T and the combination of mutations 33F and 90M,..." is vague and indefinite. Applicant states within the claim "...nucleic acid encoding HIV protease having at least one mutation chosen from 88T and the combination of mutations 33F and 90M...", wherein one mutation chosen from the combination of mutations 33F and 90M is not apparent. Said mutation, if one is present, will need to be clarified for it is unclear. Claim 7 contains abbreviations such as NNRTI, NRTI, and PI which causes the claim to be vague and indefinite unless accompanied by the full name. Also unclear designation of 103S, 118I, and 88T versus K103S, V188I, and N88T are present in claim 7.

***Claim Rejections - 35 USC § 103(a)***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jon H. Condra et al. (Journal Of Virology, Dec 1996) and Petropoulos et al., (WO 99/67427, 29 Dec. 1999)

The claimed invention is a method of evaluating the effectiveness of an antiviral therapy of an HIV infected patient. Note the page 8270; 2<sup>nd</sup> column; section "Primary viral isolates" (Condra et al.) states that IDV resistance with CIC 95 $\geq$ 400nM, than Table 1 shows N88T has CIC95 $\geq$ 3000nM in Patient O. The generic listing of mutation resistance in said Table 1 is deemed to motivate and suggest species therein such as mutant N88T. Step (i) of claim 7 is in the reference on page 73; line 4-5 (Petropoulos et al.,). Step (ii) of claim 7 is as noted (Condra et al.) cohere HIV protease with mutation N88T correlates with a drug resistance. Step (iii) of claim 7 is shown in said Table 1 in that the presence of N88T was evaluated regarding effectiveness of a therapy.

Thus, it would been obvious to some of ordinary skill in the art at the time of the instant invention to carry out the method of instant claim 7 because all of the steps therein are either described or suggested as noted above references.

**The disclosure is objected to because of the following informalities:**

On page 24 in the table 2b there is an unclear abbreviation of Pi .

*present which must be amended to deactivate.*  
On page 6 two hyperlinks are ~~objected according form paragraph 7.29.04~~

“Objection-Embedded Hyperlinks or other Browser-Executable Code”.

Appropriate correction is required

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR 1.6(d)).

The CM1 Fax Center number is either (703)308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nikolai M Galitsky, Ph.D., whose telephone number is (703)308-2422. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M. If attempts to reach the examiner by telephone are unsuccessful, the

examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Tina Plunkett, whose telephone number is (703)305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

Data:

*N.G.*  
Examiner Initials

*Ardin H. Marschel*  
ARDIN H. MARSHEL  
PRIMARY EXAMINER